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EXAMINER	
STUCKER, J	

ART UNIT	PAPER NUMBER
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DATE MAILED: 01/26/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 15-36 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.

3. ☐ Claims _____ are allowed.

4. ☒ Claims 15-36 are rejected.

5. ☐ Claims _____ are objected to.

6. ☐ Claims _____ are subject to restriction or election requirement.

7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.

8. ☐ Formal drawings are required in response to this Office action.

9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).

10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).

11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).

12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.

13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.

14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

Applicant's claim of priority to Great Britain application no. 83/24000 is acknowledged. The conditions of 35 USC 119 have not been met owing to the lack of submission of a certified copy of the priority document.

Applicant is reminded of the proper content of an Abstract of the Disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains.

If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure.

If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement.

In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof.

If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following: (1) if a machine or apparatus, its organization and operation; (2) if an article, its method of making; (3) if a chemical compound, its identity and use; (4) if a mixture, its ingredients; (5) if a process, the steps. Extensive mechanical and design details of apparatus should not be given.

The abstract should be directed to the claimed invention, i.e., antibodies.

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 C.F.R. §§ 1.52(c) and 1.56. A properly executed oath or declaration which complies with 37 C.F.R. § 1.67(a) and identifies the application by

serial number and filing date is required. The surcharge set forth in 37 C.F.R. § 1.16(e) is also required if it has not been previously paid in the application.

The declarations by inventors Chermann, Barre-Sinoussi, Rozenbaum, and Nugeyre have alterations that are not initialled and/or dated.

Claims 29-31 are rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-3 and 8 of prior U.S. Patent No. 5217861. This is a double patenting rejection.

The occurrence of an isolated and purified complex between an antibody reactive with HIV-1 proteins and HIV-1 proteins p12 or p18 is part of the reaction of combining purified proteins with antibodies reactive with the proteins.

Claims 15-21 and 32-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 7, and 9-11 of U.S. Patent No. 5217861. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to make antibodies by a routine method against proteins that are produced by the virus of interest for the purpose of detecting the presence of the virus.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 12-18 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility.

Applicant has not disclosed a use for the claimed "immunological complex" which appears to be a product formed during immunological testing. As such, this complex would also contain a component of patient sera. Applicant has not disclosed a utility for this compound as it is formed during an assay procedure. Claims to an antibody may have utility.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

The specification is not enabled for isolated and purified antibodies. There are no teachings in the specification for isolated and purified antibodies which react with p12, p15, p18, p25, p36, p42, and p80 proteins. There are no teachings in the specification for isolated and purified antibodies which react with antibodies complexed with any of the proteins from the group of p12, p15, p18, p25, p36, p42, and p80 proteins. Further, there are no teachings in the specification for isolated and purified antibodies complexed with p12 or p18. There are no teachings in the specification to enable one to make monoclonal antibodies

against p12 or p18. The specification is not enabled for labeling a complex of an antibody and HIV-1 protein.

Claims 15-36 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 31 and 35 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear where and how the label is attached to the complex of claim 31. No means are provided for the association of a labeling reagent to the immunocomplex. It is unclear if the label is attached to the antibody component or the antigen component of the complex or if it is common to both.

Claim 35 lacks an antecedent basis in claim 32 for "the detection step".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 7, and 8 are rejected under 35 U.S.C. § 102(a) as being anticipated by Barre-Sinoussi et al.

The instant invention claims the use of p18 and p25 in an immunoassay. Samples from patients suspected of being infected with HIV-1 are reacted with p18 and p25. The formation of an antigen-antibody complex is detected and indicates HIV-1 infection.

Barre-Sinoussi et al teach three proteins which are encoded by HIV-1: p13, p18, and p25. The reference discloses that sera from

AIDS and pre-AIDS patients contain antibodies which react with these three proteins. Thus, reacting the purified proteins with a serum sample selectively captures antibodies reactive with the proteins of interest to the exclusion of non-specific antibodies. Thus, Barre-Sinoussi et al teach purified complexes of antibodies and HIV-1 p13, p18, and p25.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicants are advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 15-21 and 32-36 are rejected under 35 U.S.C. § 103 as being unpatentable over Barre-Sinoussi et al.

Barre-Sinoussi et al teach purified complexes of antibodies and HIV-1 p13, p18, and p25. One having the complex obtained by the reference would be able to use routine methods to disassociate

the captured antibodies from the antigens. One could use the antibodies to capture antigens that may be in patient sera or to purify antigens known antigens. It would also be obvious and more reliable to produce hybridomas through routine methods that secrete antibodies of known and consistent specificity. Monoclonal antibodies have been used for years in the art because of their well known advantages of specificity, consistency, and availability. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the complexes of Barre-Sinoussi et al as a source of antibodies against the antigens taught by the reference. It would further be obvious to create monoclonal antibodies against the disclosed proteins.

No claims are allowed.

Papers related this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 180 Fax numbers are: (703) 308-4227 and 305-3014.

The Fax center number for assistance is: (703) 308-4744.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jeffrey Stucker whose telephone number is (703) 308-4237.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JEFFREY STUCKER

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180